REMARKS

This Amendment is intended as a full and complete response to the final Office Action dated February 2, 2009. In the Office Action, claims 8, 9, 12-19 and 23-34 are pending and stand rejected. By this amendment, claims 8, 9, 12--19, 23-30 are amended, claims 31-34 are canceled, and new claims 35-38 are added.

A. In the Specification:

The specification has been amended to conform to the drawing. Such amendment to the specification does not add any new subject matter to the application.

B. Examiner Interview:

A teleconference between Examiner Hao D. Mai, Examiner Rodriguez; the inventor, Yehia A. Massoud; and the Applicant's representatives, Steven M. Hertzberg and Thomas E. Spath, on March 25, 2009 is duly noted and appreciated. During the teleconference, proposed amendments to the claims and the relevancy of the cited prior art patents were discussed. Details of the topics discussed during the teleconference as set forth by the Examiner in the Interview Summary dated on March 30, 2009 are hereby acknowledged.

In view of the following discussion, it is submitted that none of the claims now pending in the application are indefinite, anticipated or obvious under the respective provisions of 35 U.S.C. §112, §102 and §103. Thus, it is believed that all of these claims are now in allowable form.

OBJECTIONS

A. Claim 14

Claim 14 is objected to for not indicating which claim it is dependent from. In response, claim 14 has been amended to properly depend from independent claim 8. Withdrawal of the objection is respectfully requested.

B. Claims 16 and 29

Claims 29 and 16 are objected to for reciting limitations to a treatment plan, which is a sub-combination usable with the sub-combination of the surgical guide. However, the claims fail to recite a combination in order to combine the two sub-combinations.

In response, dependent claim 29 has been amended to independent form and to change the claim scope from only a treatment plan to recite a surgical guide system which includes the treatment plan and the surgical guide. Dependent claim 16 depends from independent claim 29 and recites additional features further defining the treatment plan that are considered inventive. It is submitted that these claims now properly recite claim limitations directed to a system having a treatment plan and a surgical guide. Withdrawal of the objection is respectfully requested.

C. Claims 30 and 17-19

Claims 30 and 17-19 are objected to for reciting limitations to a cutting device, which is a sub-combination usable with the sub-combination of the surgical guide. However, the claims fail to recite a combination in order to combine the two sub-combinations.

As noted above, dependent claim 29 has been amended to independent form and to change the claim scope from a treatment plan to a surgical guide system which includes the treatment plan and the surgical guide. Dependent claim 30 and 17-19 depend from independent claim 29 and recite additional features directed to a cutting device (i.e., a bur) which are considered inventive. It is submitted that these claims now properly recite claim limitations directed to a system having a treatment plan, a surgical guide and a bur. Withdrawal of the objection is respectfully requested.

REJECTIONS

A. 35 U.S.C. §112

1. Claims 8-9, 12-19 and 23-28

In the Office Action it is stated that Claims 8-9, 12-19 and 23-28 stand rejected under 35 U.S.C. §112 as failing to comply with the written description requirement. The rejection is respectfully traversed.

Independent claims 8 and 23 have been amended to further clarify the features considered inventive. In particular, claim 8 (and similarly independent claim 23), as amended, recites:

> Surgical guide for performing a sinus elevation procedure on a specific patient's maxillary sinus by penetrating a lateral bony wall proximate a maxillary sinus of the patient, said lateral wall having an external surface, and a varying length, height and depth extending along an X-axis, a Y-axis, and a Z-axis, respectively, said surgical guide comprising:
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> a curvilinear-shaped structure for placement adjacent to and in direct and continuous contact with the external surface of said lateral wall of the maxillary sinus, said curvilinear-shaped structure having a three-dimensional window configured for placement directly over a portion of said lateral wall of the maxillary sinus and to define a surgical site to perform the sinus elevation, said window being sized to receive a dental bur and formed with a patient-specific custom-shaped peripheral edge that defines at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall, the ledge having varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site, the ledge being configured to provide continuous contact with the lateral wall along its entire length at the surgical site, wherein the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall, said window being sized greater than a diameter of the bur to permit movement, guidance and depth control of the bur in three-dimensions along the custom-shaped peripheral edge and surface contours of the window. (Emphasis added).

Support for amended claim 8 can be found in the specification, where it is stated that:

> It is well known that the lateral wall of the maxillary bone adjacent to the maxillary sinus can typically have a thickness in the range of approximately 1-5 mm, although other variations in thicknesses are known to occur. Referring to FIGS. 4 and 5, as the thickness of the lateral wall of the maxillary bone varies, the thickness of the ledge

> 810 of the window 808 of the guide 800 will also vary along the ledge 810 depending on the thickness of the lateral wall of the maxillary bone to sum to a total of about 10 mm (guide thickness plus thickness of lateral wall of maxillary sinus), since the distance between the endpoint (E) of the distal end of the cutting blade 406 and the depth guide 402 of the bur 400 is at a constant 10 mm. For example, at locations of the maxilla that have a thickness of 2 mm, then the depth of the ledge 810 of the surgical guide 800 will be 8 mm (10mm-2mm). Similarly, where portions of the maxilla bone is, for example, 5.1 mm thick, then the ledge 810 will have a depth of 4.9 mm (10mm-5.1mm), and so forth. Accordingly, the thickness of the window ledge varies to conform to the unique shape and dimensions of the lateral wall of the patient's maxilla bone as it changes at each position along the X-Y or Y-X axes. (Emphasis added, See clean version of substitute specification, beginning page 19, paragraph 0048).

It is submitted that independent claims 8 and 23 fully satisfy the written description requirements under 35 U.S.C. §112 and are patentable thereunder. Furthermore, claims 9, 12-19 and 24-28 depend either directly or indirectly from independent claims 8 and 23 and recite additional features considered inventive. Accordingly, it is submitted that these claims also fully satisfy the written description requirements under 35 U.S.C. §112 and are patentable thereunder. Withdrawal of the rejection is respectfully requested.

2. Claims 13-15

Claims 13-15 stand rejected under 35 U.S.C. §112 a being indefinite. The rejection is respectfully traversed.

Claim 13 has been amended to provide proper antecedent basis for the limitation of "said inferior ... ledge portion". Furthermore, dependent claims 14 and 15 have been amended to recite a singular peripheral edge, which has proper antecedent basis derived from independent claim 8.

Accordingly, it is submitted that these dependent claims 13-15 are not indefinite and fully satisfies the requirements under 35 U.S.C. §112 and are patentable thereunder. Withdrawal of the rejection is respectfully requested.

B. 35 U.S.C. §102

Claims 23 - 28

In the Office Action, it is stated that claims 23-38 are rejected under 35 U.S.C. §102 as being anticipated by US Patent No. 5,320,529 to Pompa (hereinafter "the '529 patent"). The rejection is respectfully traversed.

As a preliminary matter, we believe that it would be helpful to review the appropriate standard under 35 U.S.C. § 102 for analyzing the features of a claim with respect to the prior art. It is well settled that "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). The cited reference fails to disclose each and every element of the claimed invention, as arranged in the claim.

Independent claim 23, as amended, recites:

> A method of performing sinus elevation surgery to penetrate a bony lateral wall proximate a maxillary sinus of a specific patient, comprising:
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> providing a treatment plan having three-dimensional images which characterize a plurality of bony walls including the lateral wall defining a portion of the maxillary sinus and maxillary bone structures of said patient, said plurality of walls having dimensions, shape, and contours formed along surface portions of the walls that are unique to the patient; and
>
> providing a customized surgical guide based on said treatment plan for placement adjacent to and in direct contact with said lateral wall of the patient's maxillary sinus, said guide having a three-dimensional window that defines a surgical site, said window being configured to receive and sized greater than a dental bur which is used to penetrate the lateral wall, said window formed by a customized peripheral edge defining a customized ledge that is elongated in shape, said ledge further including customized surface contours that are positioned to correspond to and align with the uniquely shaped contours formed along external surface portions of the lateral wall, the length of the ledge being configured for continuous contact in its entirety with the lateral wall at the surgical site of the patient, said ledge having a customized thickness to guide and control the depth of

penetration of the distal end of the bur while the bur moves in three dimensions along the elongated ledge. (Emphasis added).

The Pompa patent fails to teach, disclose, or even suggest at least the following claimed features of:

- "said window being configured to receive and sized greater than a dental bur";
- "a customized peripheral edge defining a customized ledge that is elongated in shape";
- "the ledge being configured for continuous contact in its entirety with the lateral wall at the surgical site of the patient"; and
- "said ledge having a customized thickness to guide and control the depth of penetration of the distal end of the bur while the bur moves in three dimensions along the elongated ledge."

Referring to FIGS. 5 and 8 of the present application, as the thickness of the maxilla bone varies, the thickness of the ledge 810 of the window 808 of the guide 800 will also vary along the ledge. (See substitute specification, page 19, paragraph 0048). Since at least one of the plurality of walls of the patient's maxillary bone experiences resorption, the guide includes a customized three-dimensional window that is shaped and dimensioned to correspond to and align with the uniquely shaped contours formed along surface portions of the walls defining the maxillary sinus and maxillary bone structures of the patient. The uniquely shaped contours formed along the surface portions of the walls are attributed to the resorption of the patient's bone. Further, the emulated shape and dimensions of the window are based on results acquired during the previously conducted treatment plan.

By contrast, the `529 patent discloses providing a bore that is circular in shape and sized to receive a drill bit for boring a small diameter circular hole at a fixed location in the lower jaw bone of a patient. In particular, the `529 patent discloses:

> The apparatus according to the invention for directing a bur includes a jawbone model formed by a method of scanning the jawbone with computerized tomography and constructing a stereolithographic model including a radiopaque (marker) representing the inferior alveolar nerve. The apparatus also includes a means for locating and drilling a hole in the model to avoid the radiopaque marker and a simulated implant (implant

analog) is placed into the hole. A holder is then placed into this implant analog and protrudes above this implant analog. Then a guide template is fabricated on the jawbone model including a bore formed around the holder so that when the template is now transferred and placed on the jawbone of the patient, a specifically designed drill is guided by the template bore into the jawbone along the same path as the hole in the model to avoid the nerve and forms a hole for receiving the actual implant and holder. (See the `529 patent, col. 2, line 58 to col. 3, line 7, and FIG. 5, emphasis added).

The `529 patent further discloses:

FIG. 5 shows the completed guide template 16 which is now placed on the patient's lower jawbone 20, not model 10. Surgical guide ring 25a is placed into a bore 38 of template 16 to provide a guide for drill or bur 17 as it penetrates jaw 20. Bur 17 will follow the path of site 14 which was made during model surgery when the surgeon visualized the location of opaque marker 11d which represented nerve 11a, i.e., in a vertical plane which passes through the mental foramen and is generally perpendicular to the surface of the model above and/or below the mental foramen. (See the `529 patent, col. 5, lines 33-43 and FIGS. 3 and 5)

Accordingly, the `529 patent only discloses a surgical guide having one or more bores for guiding a bur in a single direction and location to form an equally sized hole in the jaw bone of a patient. That is, the bores of the Pompa guide are circular (i.e., symmetrical) in shape and sized to (i) guide the drill (bur) into the jawbone in a fixed direction along a single axis (e.g., vertical or Z-axis) and (ii) receive the threaded implants. Thus, the bore (i.e., window) is not configured to receive and sized greater than a dental bur to permit a range of movement along the X and Y axes. The surgical guide disclosed in the `529 patent is not suitable for performing a sinus elevation procedure because the surgeon will not be able to use the guide of the `529 patent as a tracing pattern with a bur to cut along the peripheral edge (i.e., elongated ledge) of the window along the X and Y axes, since the bore (i.e., window) of the `529 patent and the bur have equal diameters. There is only one entry point in the mandible with the guide of the `529 patent.

Further, the `529 patent fails to disclose that the elongated ledge is configured for continuous contact in its entirety with the lateral wall at the surgical site of the patient. As noted above, the surgical guide includes a bore, as opposed to having a window with an elongated ledge. When the surgical guide is placed directly over the surgical site, the elongated ledge is customized

with a shape and dimensions such that its entire surface area is of the elongated ledge is in continuous contact with the lateral wall at the surgical site. This feature is not disclosed, taught or even suggested in the `529 patent to Pompa.

Moreover, the `529 patent fails to disclose "said ledge having a customized thickness to guide and control the depth of penetration of the distal end of the bur while the bur moves in three dimensions along the elongated ledge." The surgical guide of the `529 patent includes a bore, as opposed to a customized window having an elongated ledge. Accordingly, the bore will not permit the bur to move in three dimensions along the elongated ledge. Rather, the bore of the `529 patent will only permit the bur to move in a single direction along a single axis (e.g., the Z-axis).

The Applicant's surgical guide is completely different from the surgical guide of the `529 patent. In particular, the present invention includes a three-dimensional window defining the surgical site which is configured to receive and sized greater than a dental bur, the window includes a customized peripheral edge defining a customized ledge that is elongated in shape, the ledge is configured for continuous contact in its entirety with the lateral wall at the surgical site of the patient, and the ledge has a customized thickness to guide and control the depth of penetration of the distal end of the bur while the bur moves in three dimensions along the elongated ledge. This three-dimensional cut allows for removal of a block of bone that is dimensioned larger than the cutting device (e.g., bur) itself, which is impossible to achieve with a bore. Therefore, the `529 patent fails to disclose each and every element of the claimed invention, as arranged in the claim.

As such, it is submitted that claim 23 is not anticipated and fully satisfies the requirements under 35 U.S.C. § 102 and is patentable thereunder. Furthermore, claims 24-28 and new claim 38 depend from independent claim 23 and recite additional inventive features. As such, and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 102 and are patentable thereunder. Withdrawal of the rejection is respectfully requested.

C. 35 U.S.C. §103

1. Claims 8, 9, 12-15 and 31-34

In the Office Action, it is stated that claims 8, 9, 12-15 and 31-34 are rejected under 35 U.S.C. §103 as being obvious over US Patent No. 5,558,622 to Greenberg (hereinafter "the `622 patent"). The rejection is respectfully traversed.

a) Claims 31-34

Claims 31-34 have been canceled. Therefore, the rejection is considered moot.

b) Claims 8, 9 and 12-15

Independent claim 8 has been amended to include additional features considered inventive. In particular, independent claim 8, as amended, recites:

> Surgical guide for performing a sinus elevation procedure on a specific patient's maxillary sinus by penetrating a lateral bony wall proximate a maxillary sinus of the patient, said lateral wall having an external surface, and a varying length, height and depth extending along an X-axis, a Y-axis, and a Z-axis, respectively, said surgical guide comprising:
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> a curvilinear-shaped structure for placement adjacent to and in direct and continuous contact with the external surface of said lateral wall of the maxillary sinus, said curvilinear-shaped structure having a three-dimensional window configured for placement directly over a portion of said lateral wall of the maxillary sinus and to define a surgical site to perform the sinus elevation, said window being sized to receive a dental bur and formed with a patient-specific custom-shaped peripheral edge that defines at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall, the ledge having varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site, the ledge being configured to provide continuous contact with the lateral wall along its entire length at the surgical site, wherein the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall, said window being sized greater than a diameter of the bur to permit movement, guidance and depth control of the bur in

three-dimensions along the custom-shaped peripheral edge and surface contours of the window. (Emphasis added).

As a preliminary matter, we believe that it would be helpful to review the appropriate standard under 35 U.S.C. § 103 for analyzing the features of a claim with respect to the prior art. It is well settled that [t]he test under 35 U.S.C. § 103 is not whether an improvement or a use set forth in a patent would have been obvious or non-obvious; rather the test is whether the claimed invention, considered as a whole, would have been obvious. Moreover, the invention as a whole is not restricted to the specific subject matter claimed, but also embraces its properties and the problem it solves. In re Wright, 6 USPQ 2d 1959, 1961 (Fed. Cir. 1988) (emphasis added).

The mandibular retractor of the `622 patent fails to teach, disclose, suggest, motivate or predict the Applicant's present invention as a whole. In particular, the Applicant's surgical guide includes a three-dimensional window that is sized greater than a diameter of a dental bur, the window has a patient-specific custom-shaped peripheral edge that defines at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall, the ledge has varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site, the ledge is configured to provide continuous contact with the lateral wall along its entire length at the surgical site, wherein the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall.

Referring to page 17, paragraph 0044 to page 18, paragraph 0045 of the present application discloses that:

> Referring now to FIG. 8, the surgical guide 800 is curvi-linear in shape and is sized and shaped to correspond to the upper jaw (maxilla) and sinus shape of a particular patient, as determined by the CT scan and 3-D imaging software previously administered to the patient. As illustratively shown in the drawing, the surgical guide 800 includes a curved lower portion 802 having an upper surface 804 adapted for positioning along the lower edge of the maxilla (alveolar ridge) or the upper teeth (e.g., molars). The curved lower portion extends in an upward direction to form a second portion 806 having an overall height "H" an, overall width "W", and an overall thickness or depth "D".

> The upward extending second portion 806 includes at least one orifice or window 808 illustratively having a somewhat rectangular shape. The peripheral edges of the window 808 form a ledge 810 that is used in conjunction with a bur (FIG. 4) for performing the osteotomy, as discussed below in further detail. The size and shape of the window 808, as well as the depth or thickness of the ledge 810 are formed to correspond with the results of the CT scan and 3-D imaging software used for planning the osteotomy for a particular patient, such that the lower portion of the ledge 810 is aligned with and conforms to the shape of the bony floor of the sinus cavity and coronal portion of the maxilla. (Emphasis added).

The mandibular retractor of the `622 patent is nothing more than a mass-produced, off-the-shelf, hand tool that must be held by the doctor or assistant during a procedure. Moreover, it is used merely as a "pry-bar" during a procedure that is in no way related to the sinus elevation procedure recited in the present claims. As such, the `622 patent teaches away from the presently claimed surgical guide, since the shape of the aperture 60 formed in the retractor does not include (i) a custom-shaped peripheral edge, (ii) that defines at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall, (iii) the ledge has varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site, (iv) the ledge is configured to provide continuous contact with the lateral wall along its entire length at the surgical site, and (v) the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall.

The `622 patent discloses:

> [A] mandibular retractor which is inserted into the patient's mouth and has a curvilinearly-shaped retractor blade to retract the cutaneous region away from the mandible laterally. The retracting blade has an aperture which allows surgical instruments to be inserted through an incision in the cutaneous region, through the aperture, and to the mandible. The retractor also has an arcuate distal portion which may be located under and behind the mandible. The retractor allows a surgeon to retract with one hand and view the surgical site by looking down in to the mouth. The surgeon's other hand is free to operate surgical instruments such as a drill or screwdriver. (See `622 patent, col. 3, lines 25-37).

The `622 patent is completely silent with regard to a patient-specific custom-shaped peripheral edge. Rather, the retractor of the `622 patent is the same for every patient that would encounter such device. There is absolutely no customization of the retractor based on the bone structure of each individual patient. Every retractor of the Greenberg patent is identical in shape and dimension without any regard to unique structural aspects of the lateral wall of each specific patient. As such, there is no teaching, disclosure, suggestion or hint of a "patient-specific custom-shaped peripheral edge".

That is, the `622 patent does not teach, disclose, suggest or even predict the claimed feature of "at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall". Referring to FIGS. 4 and 17, the elongated ledge forming aperture 60 of the Greenberg patent extends along the Y-axis of the lateral wall. The only part of the aperture 60 extending along the X-axis of the lateral wall of the patient (see Greenberg, FIG. 17) is the lower curved portion. This arcuate distal portion of the Greenberg retractor prevents the guide from being positively seated against the lateral wall of the patient, as the curvature interferes with any positive fit against the lateral wall. As such, there is no teaching, disclosure, suggestion or hint of "at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall".

Additionally, the `622 patent does not teach, disclose, suggest or even predict the claimed feature of "the ledge having varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site". The Greenberg patent is completely silent with respect to varying surface contours, and more specifically, surface contours formed in Z-Y and X-Y planes extending along the length to correspond to and align with surface contours formed in the Z-Y and X-Y planes of the lateral wall at the surgical site. Referring to the Greenberg drawings, the mandible retractor has a uniformly shaped retractor blade 54 and its elongated ledge of the window is completely devoid of any surface contours formed on the surface areas. In fact, the retractor blade 54 has a smooth surface without any contours. By contrast, referring to FIG. 8 of the present application, the ledge includes surface contours formed in the X-Y and Z-X planes extending along

the length. As such, there is no teaching, disclosure, suggestion or even hint of "the ledge having varying surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site".

Further, the `622 patent does not teach, disclose, suggest or predict the claimed feature of "the ledge being configured to provide continuous contact with the lateral wall along its entire length at the surgical site". Every individual patient has a uniquely shaped maxillary bone and the resorption that occurs on the lateral wall of the maxillary bone is different for each patient as well. Thus, the present invention provides a surgical guide that has an elongated ledge with a shape, dimension and surface contours that conform to the shape, dimensions and surface contours of the lateral wall for a specific patient. In this manner, when the surgical guide is placed over the lateral wall to define the surgical site, the ledge is in continuous contact with the lateral wall along its entire length at the surgical site. By contrast, the surgical guide of Greenberg does not have any structural design, shape or configuration that mimics the shape, dimensions and surface contours of the lateral wall for a specific patient. Therefore, there is no teaching, disclosure, suggestion or hint of "the ledge being configured to provide continuous contact with the lateral wall along its entire length at the surgical site".

Moreover, the `622 patent does not teach, disclose, suggest or predict the claimed feature in which "the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall". Referring to FIGS. 4 and 17 of Greenberg, the peripheral edge forming the ledge of the aperture 60 does not have a variable depth in the Z-X plane. Rather, the thickness is a constant thickness. Moreover, there are no thickness variations disclosed or suggested in the Greenberg patent that "correspond to thickness variations along the Z-X plane of the patient's lateral wall. In other words, the Greenberg retractor does not allow for variable depth control over a variable thickness of the lateral wall. Therefore, there is no teaching, disclosure, suggestion or hint of "the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall".

The aforementioned customized structural differences are clearly not taught, disclosed, suggested or even hinted in the cited Greenberg patent. The technical problem addressed by the Applicant was to provide a method, apparatus and system for retracting soft tissue in order to perform a specialized surgical procedure, i.e., a sinus elevation procedure on a specific patient's maxillary sinus by penetrating a lateral bony wall proximate a maxillary sinus of the patient. By contrast, the technical problem addressed by Greenberg is a method and device for fixating a fractured mandible. Greenberg solved this problem by providing a specialized mandibular retractor which improves the surgeon's access and visibility of the surgical site, and to retract soft tissue prior to fixating a fractured mandible, thereby reducing the need for a surgical assistant. (See Greenberg, col. 1, lines 8-14).

When undertaking a fair reading of the Greenberg patent, a person of ordinary skill in the art would never had been prompted to solve the technical problem that the Applicant solved, because in the Greenberg patent, which belongs to a different technical field with respect to the Applicant, there is absolutely no disclosure, teaching or even hint about how to solve the technical problem addressed by the Applicant.

In particular, a person skilled in the art at the time the invention was made is a dental surgeon who performs sinus elevation procedures using specialized tools of the trade. The technical field of the Greenberg patent would not have prompted a need or desire to provide a surgical guide for performing an osteotomy and sinus elevation in a manner addressed by the Applicant, since the ability to perform an osteotomy and a sinus elevation has never been an issue in the Greenberg patent. Rather, Greenberg is limited to addressing a device and procedure to treat a fractured mandible jaw bone.

The Examiner notes that Greenberg fails to disclose the ledge having a variable thickness. However, the Examiner states that changes in the shape, configuration and/or dimension is a design choice well within the skill of the person of ordinary skill in the art. Thus, the Examiner asserts that the structure of Greenberg in combination with the alleged "design choice" knowledge of a person of ordinary skill in the art is sufficient to formulate an obviousness rejection.

It is submitted that the configuration and/or dimensions are not merely predictable design choices well within the skill of a person of ordinary skill in the art. Rather, the shapes, configuration and dimensions are clearly critical structural elements that are necessary to conform to the shape and dimensions of the lateral wall of a specific patient. Each surgical guide is unique in shape for a particular patient. Since Greenberg never addressed the technical problem of performing a sinus elevation, it is inconceivable that a person of ordinary skill in the art would simply provide ordinary shape and dimension modifications to the mandibular retractor of Greenberg to conceive, develop and reduce to practice a surgical guide such as the Applicant's invention with the unique shapes, dimensions and configurations for a specific patient.

Applicant respectfully submits that it would be improper to assert this rejection against the claims, since the cited reference does not disclose all of the limitations of the claimed invention, nor does the reference taken alone or in combination with the Examiner's conclusion opinion teach, suggest or even predict the changes that would produce the claimed invention. The U.S. Court of Appeals Federal Circuit has affirmed that it is improper to find that a claimed invention is an obvious design choice where the claimed structure and the function it performs are different from the prior art. *In re Chu*, 36 USPQ2d 1089 (Fed. Cir. 1995) (quoting from *in re Gal*, 25 USPQ2d 1076 (Fed. Cir. 1992)). Even simple changes from the prior art are not properly considered to be obvious matters of design choice or "obvious exercise of mechanical skill" where there is no teaching or suggestion in the prior art to make the changes.

In this case, the contours, curvature, variations in thickness and other surgical guide dimensions have never been addressed or were determinable by those skilled in the art. In fact, if these shape had readily been determinable by those of ordinary skill in the art, then the problems of removing too little or not enough bone in the lateral wall during the osteotomy, precisely locating the sinus floor, or damaging the Schneiderian membrane of the maxillary sinus would not be a present issue. Therefore, the Applicant's claimed structure and the function it performs is different from the retractor disclosed in Greenberg.

Moreover, the Examiner has completely disregarded any functional aspects of the claimed invention by dismissing its patentable weight because it merely recites intended use. It is well settled that "the characterization 'functional', as used by the Patent Office and argued by the parties, [indicates] nothing more that the fact that an attempt is being make to define something ... by what it *does* rather than by what it *is* (as evidence by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. Indeed we have even recognized in the past the practical *necessity* for the use of functional language." *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (C.C.P.A. 1971). It is submitted that the Examiner must afford patentable weight to the functional limitations, even if the functional limitations are the only limitations that are non-obvious over the prior art.

In other words, the operational and other functional aspects of the structural elements of the surgical guide must be given patentable weight and therefore, have significant relevance for determining whether the claimed invention, considered as a whole, would have been obvious. In this case, claim 8, as amended, recites that "said curvilinear-shaped structure having a three-dimensional window configured for placement directly over a portion of said lateral wall of the maxillary sinus and to define a surgical site to perform the sinus elevation". The claimed feature that the surgical guide is configured for placement over a portion of the lateral wall is a functional aspect of the present invention which is to be given patentable weight in view of the Greenberg patent. The Greenberg patent is not only structurally different than the present invention, but includes an aperture 60 that is designed/configured for placement over a portion of the mandible bone of the patient.

Moreover, the `622 patent only discloses that the aperture 60 is sized to allow a surgical device to extend therethrough. The aperture 60 is limited to only providing access there-through, as opposed to providing a customized ledge for supporting and guiding a cutting device while performing the surgery. In particular, the `622 patent only discloses "[t]he retracting blade has an aperture which allows surgical instruments to be inserted through an incision in the cutaneous region, through the aperture, and to the mandible." (See the `622 patent, col. 3, lines 29-32, Emphasis added). The aperture 60 of Greenberg does not function as a guide. More

importantly, the shape and size of the device precludes its placement in proximity to a patient's maxillary bone because of the presence of the inside of the patient's cheek.

Even if the retractor of the `622 patent could somehow be used to perform a sinus elevation procedure (and it is again reasserted that the retractor cannot be used without detrimental risk to the patient), it would require a dental surgeon to perform the surgery by approximating where the floor of the sinus is located, where the superior portion is located, as well as where the anterior wall and the posterior wall are located. In addition, the variable depth of the lateral wall of the sinus could only be accessed with the experience and visual sense of the surgeon, without exact measurements as to the varying thickness of the osteotomy as it moved along the X-Y axis. Thus, the retractor of the `622 patent defeats the very purpose of the present invention.

Accordingly, the Applicant's surgical guide differs from the mandibular retractor of the `622 patent because the shape and dimensions of the surgical guide of the present invention are customized and unique for each patient, as opposed to being a standardized shape that is used for all patients. The shape and dimensions are determined based on a treatment plan, for example, utilizing a CT scan and 3-D imaging software to provide details of the patient's maxillary sinus and bone structures. The three-dimensional window formed in the surgical guide is dimensioned and shaped to correspond to and align with the unique shape of the maxillary bone of a patient, as opposed to being shaped merely as a matter of design choice. Thus, the Applicant's claimed surgical guide must be properly aligned and secured laterally against the patient's maxillary bone to allow the surgeon to perform the procedure with minimal risk of collateral damage to the surrounding surgical areas (e.g., Schneiderian Membrane).

Accordingly, it is submitted that the `622 patent fails to disclose or suggest the claimed feature of "said curvilinear-shaped structure having a three-dimensional window configured for placement directly over a portion of said lateral wall of the maxillary sinus and to define a surgical site to perform the sinus elevation, said window being sized to receive a dental bur and formed with a patient-specific custom-shaped peripheral edge that defines at least one elongated ledge having a length that extends in a direction along the X-axis of the lateral wall, the ledge having varying

surface contours formed in X-Y and Z-X planes extending along the length to correspond to and align with surface contours formed in the X-Y and Z-X planes of the lateral wall at the surgical site, the ledge being configured to provide continuous contact with the lateral wall along its entire length at the surgical site, wherein the ledge includes a variable depth in the Z-X plane and is configured to directly correspond to thickness variations along the Z-X plane of the patient's lateral wall, said window being sized greater than a diameter of the bur to permit movement, guidance and depth control of the bur in three-dimensions along the custom-shaped peripheral edge and surface contours of the window". Therefore, the `622 patent fails to disclose or suggest the present invention as a whole.

As such, it is submitted that independent claim 8 is not obvious and fully satisfies the requirements under 35 U.S.C. § 103 and is patentable thereunder. Furthermore, claims 9, 12-15 and new claims 35-37 depend, either directly or indirectly, from independent claim 8 and recite additional features thereof. As such, and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 103 and are patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

2. Claims 29 and 16

In the Office Action, it is stated that claims 29 and 16 are rejected under 35 U.S.C. §103 as being obvious over US Patent No. 5,558,622 to Greenberg (hereinafter "the `622 patent") in view of US Patent No. 5,320,529 to Pompa. The rejection is respectfully traversed.

Claim 29 has been amended from dependent form to independent form to further define a surgical guide system for performing sinus elevation on a lateral wall of a maxillary bone of a specific patient. In particular, claim 29, as amended, recites:

> A surgical guide system for a performing sinus elevation procedure by penetrating an outer surface of an irregularly-shaped lateral wall of a maxillary bone forming a maxillary sinus of a specific patient, the system comprising:
>
> a treatment plan including a CT-scan and three-dimensional images which characterize a plurality of walls defining the maxillary sinus and maxillary bone structures of the patient, said plurality of walls having irregular dimensions, shapes, and contours formed along surface portions of the walls that are unique to each patient, said lateral wall having a length extending along an X-axis, a height extending along a Y-axis, and a depth

extending along a Z-axis, said lateral wall having a convex-shape extending along the X-axis;

a curvilinear-shaped structure having a three-dimensional window for placement directly over a portion of the outer surface of the patient's lateral wall of the maxillary bone to define a surgical site to perform the sinus elevation, said window being sized to receive a dental bur and formed with a customized peripheral edge that defines at least one elongated ledge having a length that extends along the X-axis of the lateral wall, the elongated ledge being concave in shape at least along its inner surface and along the X-axis, and having a surface contour that interfaces with and conforms to a surface contour of the convex-shaped lateral wall of the patient, wherein said elongated ledge is configured for continuous contact along its entire length with the lateral wall at the surgical site; said elongated ledge having a customized variable depth along the Z-axis which corresponds to and aligns with thickness variations of the patient's lateral wall, said window being sized greater than a diameter of the bur to permit movement, guidance and depth control of the bur in three-dimensions along the customized peripheral edge and surface contours of the window; and

wherein the curvilinear-shaped structure and window are customized in shape and dimension to conform to the unique and irregularly-shaped and dimensioned lateral wall of the patient's maxillary bone at the surgical site, as determined by the CT-scan and three-dimensional images of the treatment plan. (Emphasis added).

The combination of Greenberg and Pompa fail to teach, suggest, motivate, disclose, or predict the claimed features of "a customized peripheral edge that defines at least one elongated ledge having a length that extends along the X-axis of the lateral wall", "the elongated ledge being concave in shape at least along its inner surface and along the X-axis, and having a surface contour that interfaces with and conforms to a surface contour of the convex-shaped lateral wall of the patient", "wherein said elongated ledge is configured for continuous contact along its entire length with the lateral wall at the surgical site," and "said elongated ledge having a customized variable depth along the Z-axis which corresponds to and aligns with thickness variations of the patient's lateral wall".

The Pompa patent discloses that surgeons can use information from a standard CT scan to approximate the angle of the site for the implant. (See Pompa, col. 2, lines 1-3). However, as further noted in Pompa, this method of using a CT scan for approximating the angle of the site for the implant "presents a risk of damage to the inferior alveolar nerve which can result in altered or no sensation to the lip and chin on the affected side ...." (See Pompa, col. 2, lines 3-12).

As described above, the Greenberg patent is devoid of any teaching, suggestion, motivation, hint or predictability of "a customized peripheral edge that defines at least one elongated ledge having a length that extends along the X-axis of the lateral wall". Rather, the elongated peripheral edge extends along the Y-axis of the lateral wall of the patient. Thus, the CT scan of Pompa is not used in any manner to provide at least one elongated ledge having a length that extends along the X-axis on the retractor blade of Greenberg. In other words, the combination of the CT scan of Pompa and the retractor of Greenberg would still result in approximating the location of the surgical site. By contrast, the Applicant's claimed invention obviates any need to approximate the location of the surgical site on the lateral wall of the patient's maxillary bone.

Furthermore, the Greenberg patent is devoid of any teaching, suggestion, motivation, hint or predictability of "the elongated ledge being concave in shape at least along its inner surface and along the X-axis, and having a surface contour that interfaces with and conforms to a surface contour of the convex-shaped lateral wall of the patient". In fact, the retractor blade 54 of the Greenberg patent is convex in shape. As such, it is impossible for the retractor blade 54 of the Greenberg patent to have an "elongated ledge [ ] configured for continuous contact along its entire length with the lateral wall at the surgical site". That is, since the lateral wall of the patient is convexly shaped, the surgical guide must be concavely shaped in order for the elongated ledge to be in continuous contact along its entire length with the lateral wall at the surgical site. Since the convex shaped retractor blade 54 of Greenberg is placed against the convex-shaped lateral wall of the patient, the retractor blade of Greenberg will only contact the convexly shaped lateral wall at a single point along the elongated ledge, thereby negating any possibility of the inner surface of the guide having continuous contact and positive seating with the outer surface of the lateral wall. Thus, the CT scan of Pompa is not used to configure an elongated ledge of the retractor blade of Greenberg in any manner to have a concave shape at least along its X-axis. Accordingly, the retractor blade of Greenberg in combination with the CT scan of Pompa would still result in the surgeon having to approximate the location of the surgical site on the lateral wall of the patient's maxillary bone.

Moreover, the Greenberg patent is devoid of any teaching, suggestion, motivation, hint or predictability of "said elongated ledge having a customized variable depth along the Z-axis which corresponds to and aligns with thickness variations of the patient's lateral wall". As described above, the retractor blade 54 of Greenberg has a constant thickness. Again, the CT scan of Pompa is not used to configure an elongated ledge of the retractor blade of Greenberg in any manner to have a customized variable depth along the Z-axis which corresponds to and aligns with thickness variations of the patient's lateral wall. Thus, the retractor blade of Greenberg in combination with the CT scan of Pompa would still result in the surgeon having to approximate the location of the surgical site on the lateral wall of the patient's maxillary bone.

The combination of Greenberg and Pompa only discloses a system that provides CT scans to identify the location of the sinus floor of a specific patient, and an "off-the-shelf", non-customized retractor that does not conform in any manner to the unique shape and dimensions of the lateral wall (i.e., sinus floor) of the specific patient for which such retractor would ill-advisedly be used to perform the sinus elevation. Accordingly, the combination of Greenberg and Pompa fails to teach, disclose, suggest or even predict the claimed feature of "wherein the curvilinear-shaped structure and window are customized in shape and dimension to conform to the patient's uniquely shaped and dimensioned lateral wall of the maxillary bone at the surgical site, as determined by the CT-scan and three-dimensional images of the treatment plan which was previously prepared for the patient." Therefore, the combination of Greenberg and Pompa fails to teach, disclose, suggest or predict the present invention as a whole.

As such, it is submitted that independent claim 29 is not obvious and fully satisfies the requirements under 35 U.S.C. § 103 and is patentable thereunder. Furthermore, claim 16 depends from independent claim 29 and recites additional features thereof. As such, and for at least the same reasons discussed above, it is submitted that this dependent claim also fully satisfies the requirements under 35 U.S.C. § 103 and is patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

3. Claims 17-19 and 30

In the Office Action, it is stated that claims 17-19 and 30 are rejected under 35 U.S.C. §103 as being obvious over US Patent No. 5,558,622 to Greenberg (hereinafter "the `622 patent") in view of US Patent No. 6,235,035 to Boukhris. The rejection is respectfully traversed.

As noted above, Claim 29 has been amended from dependent form to independent form to define a surgical guide system for performing sinus elevation on a lateral wall of a maxillary bone of a specific patient. Furthermore, claims 17-19 and 30 depend from independent claim 29 and recited additional features considered inventive. In particular, dependent claims 17-19 and 30 are directed to features associated with the bur used for penetrating the lateral wall of the maxillary bone while performing a sinus elevation on the patient.

As described above, the combination of Greenberg and Pompa fail to teach, disclose, suggest or predict the present invention as recited in independent claim 29 as a whole. Moreover, the Boukhris patent fails to bridge the substantial gap as between the Greenberg and Pompa patents, and the Applicant's claimed invention.

In particular, the Boukhris patent only discloses a bone recovering surgical drill having a fixed stop. (See Boukhris, col. 1, line 35 to col. 2, line 4, and FIG. 1). The combination of Greenberg, Pompa and Boukhris fails to teach, disclose, suggest or even predict the claimed feature of "wherein the curvilinear-shaped structure and window are customized in shape and dimension to conform to the patient's uniquely shaped and dimensioned lateral wall of the maxillary bone at the surgical site, as determined by the CT-scan and three-dimensional images of the treatment plan which was previously prepared for the patient." Moreover, the combination of the cited references fails to teach, disclose, suggest or predict the claimed features of "a curvilinear-shaped structure having a three-dimensional window for placement directly over a portion of the patient's lateral wall of the maxillary sinus to define a surgical site to perform the sinus elevation, said window being sized to receive a dental bur and formed with a customized peripheral edge that defines at least one elongated ledge having a length that extends along the X-axis of the lateral wall, the elongated ledge being concave in shape at least along the X-axis and having a surface contour that conforms to a surface contour of the convex-shaped lateral wall of the patient, wherein said

elongated ledge is configured for continuous contact along its entire length with the lateral wall at the surgical site; said elongated ledge having a customized variable depth along the Z-axis which corresponds to and aligns with thickness variations of the patient's lateral wall, said window being sized greater than a diameter of the bur to permit movement, guidance and depth control of the bur in three-dimensions along the customized peripheral edge and surface contours of the window." Since none of the customized features recited in these dependent claims is disclosed, taught, suggested or predictable from the combination of the three cited references, the retractor blade of Greenberg in combination of the CT scan of Pompa and the bur of Boukhris would still result in the surgeon having to approximate the location of the surgical site on the lateral wall of the patient's maxillary bone. Therefore, the combination of Greenberg, Pompa and Boukhris fails to teach, disclose, suggest or predict the claimed features of the present invention as a whole.

As such, it is submitted that these dependent claims 7-19 and 30 are not obvious and fully satisfy the requirements under 35 U.S.C. § 103 and are patentable thereunder. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendments to the claims, arguments and discussion presented herein, it is respectfully submitted that this Amendment responds to all of the issues raised in the Office Action. Thus, it is submitted that all of the claims are in condition for allowance. Accordingly, favorable reconsideration of this application and its prompt issuance of a Notice of Allowance are earnestly solicited.

If, however, the Examiner believes that there are any unresolved issues in any of the claims now pending in the application, we respectfully request that the Examiner telephone Steven M. Hertzberg at (212) 885-9223 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

Request for Continued Examination

A Request for Continued Examination and this firm's check for the fees is also being filed with this Amendment. The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, due by reason of this Amendment to Deposit Account No. 01-0035.

All correspondence should continue to be directed to the address below.

Respectfully submitted,

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